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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/697,036

10/31/2003

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1656

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/697,036	NAKAJIMA, HIROKI	
	<b>Examiner</b>	<b>Art Unit</b>	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-10 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

Claims 15-22 have been canceled. Claims 1-10 are still at issue and are present for examination. Claims 11-14 are withdrawn as drawn to non-elected invention.

Applicants' arguments filed on 4/16/2007, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transformed budding yeast cell deficient in hybrid-sensor kinase by a DNA encoding an osmosensing histidine kinase with no transmembrane domain, does not reasonably provide enablement for preparing all transformed bacterial, yeast or plant cells deficient in hybrid-sensor kinase by a DNA encoding at least one osmosensing histidine kinase from any source or species.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The specification fails to teach which osmosensing histidine kinase (lacking transmembrane domains) encoding genes (or gene families) are likely to result in expression products that can cure the deficiency of bacterial, plant or yeast cells lacking at least one hybrid sensor kinase. No examples of such genes (or gene families) are provided either. According to applicant himself, in response of 4/16/2007 (see Nagahashi et al., Microbiology, 1998, 144, 425-432) the pathways of osmosensing signal transduction and their members (constituents) are extremely divergent such that they may even be different among the different species of a single host such as yeast.

Therefore, due to lack of sufficient guidance and examples provided and due to unpredictability of prior art as which osmosensing histidine kinase encoding genes are likely to cure the hybrid sensor kinase deficiency of all yeast, bacterial and plant cells one of skill in the art has to go through the burden of undue experimentation in order to screen for those polynucleotides that are capable of curing the hybrid sensor kinase deficiency in said host cells and as such the claims go beyond the scope of the disclosure. Since osmosensing histidine kinase encoding genes that are likely to cure the hybrid sensor kinase deficiency of all yeast, bacterial and plant cells are not fully enabled, transformed cells with such genes are also not fully enabled.

Claims 1-3, 5-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 and its dependent claims 2-3 and 5-

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10 are directed to a **genera** of hybrid sensor kinase deficient cells from bacterial, plant or yeast origin into which a DNA encoding an osmosensing histidine kinase having no transmembrane is introduced in a functional form, which have been inadequately described in the specification.

The specification fails to teach the structural requirements of DNA sequences which may complement the hybrid sensor kinase deficiency in the diverse family of bacterial and plant (including yeast) cells. Given the fact that osmosensing transduction pathways (and their constituents), as admitted by applicant (see Nagahashi et al., cited above), are so diverse that even allow for pathway diversity in a single plant subfamily (such as yeast), some additional guidance about the structure of osmosensing histidine kinase genes, that may be utilized in the instant invention, is required that is currently lacking in the specification. All applicant provides is the type of osmosensing histidine kinase genes which may operate in budding yeast (i.e. **a single species**), which is inadequate to define all the members of the osmosensing histidine kinase encoding polynucleotide genus/genera and transformed cells comprising them, as broadly claimed. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Since the genera of histidine kinase encoding genes that are functional in transformed hybrid-sensor kinase deficient cells are inadequately described, cells transformed with such products are also inadequately described.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cui et al. (cited previously) according to previous office action. In traversal of this rejection applicant argues that the prior art cited discloses *B. fuckeliana* which is a filamentous fungi and instant claim 1 recites a cell that is a bacterial cell, yeast cell or plant cell. Therefore according to applicant, Cui no longer anticipates the invention.

This argument was fully considered but was found **unpersuasive** because, as applicant may be aware, fungi are from plant family and yeast is a type of fungi. Therefore, applicant's amendment fails to overcome the art and the rejection remains for the reasons of record.

***Allowable Subject Matter***

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This is because the invention is free of prior art. Further, the prior art does suggest any hybrid-sensor kinase deficient budding yeast cells that have been transformed with a DNA encoding an osmosensing kinase having no transmembrane domain. Therefore said claim is also non-obvious.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Monshipouri  
Maryam Monshipouri Ph.D.

Primary Examiner

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